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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/677,822      | 10/02/2000  | David A. Estell      | GC527C2             | 3611             |

5100 7590 10/06/2003

GENENCOR INTERNATIONAL, INC.  
ATTENTION: LEGAL DEPARTMENT  
925 PAGE MILL ROAD  
PALO ALTO, CA 94304

EXAMINER

SAUNDERS, DAVID A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1644

20

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

677,822

Applicant(s)

ESTAL et al

Examiner

SAUNDERS

Group Art Unit

164X

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1, 4 - 8, 31 is/are pending in the application.  
Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1, 4 - 5, 7, 31 is/are rejected.
- ☒ Claim(s) 6, 8 is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

Art Unit: 1644

Amendment of 6/16/03 has been entered; claims 1, 4-8 and 31 are pending and under examination.

The amendment has entered no new matter.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment has overcome all bases of rejection previously stated under 35 U.S.C. 101 and 112 and of objection under 37 CFR 1.75.

Regarding prior art rejections of record, the amendment has overcome the 102(b) rejection over Moritsen et al. The 102(a) rejection over Landry et al. is maintained infra.

Claims 1, 4-5, 7 and 31 are rejected under 35 U.S.C. 102(a) as being anticipated by Landry et al. (WO 99/06061).

The rejection of record is applicable to amended claim 1 and new claim 31 because, in the embodiment in which the inserted sequence overlaps the N-terminus of the epitope, there would be substitutions within the epitope.

Applicant's response has urged that the declaration of Fiona Harding, filed under 37 CFR 1.131 has overcome. It has not because the declaration must be executed by "the inventor" –i.e. the inventive entity, which includes another person who did not sign the declaration.

Upon reconsideration of the disclosure and prior art the following new grounds of rejection are stated.

Claims 1, 4-5, 7 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipford et al. (Immunology, 84, 298, 1995).

The Immunology article of Lipford et al. corresponds to the abstract of record in the IDS filed on 2/11/02.

Lipford et al. disclose an octameric peptide from HPV protein E6. A modified form of this peptide, with I substituted for D at position 2, can be used as an effective immunogen for the generation of cytotoxic T-cells (page 299, third full para). This modified peptide induces a better T-cell response than does the unmodified peptide (Figure 2 (a) and (b)). They teach that such peptides, that have been modified to better bind MHC-class I receptors and thus induce a better T-cell response, may be useful in anti-tumor vaccines (abstract and page 302, col. 1).

The claims are properly rejected over the Lipford et al. Reference showing a modified octamer, because an octamer is considered as reasonably being within the scope of "polypeptide". Applicant's disclosure gives no definition of a "polypeptide" that sets any lower limit upon its length. Also applicant specifically teaches that the invention encompasses "peptides to be used as T-cell vaccines" (page 10, line 23).

From the above discussion of the teachings of the reference, it is clear that dependent claims 4-5 and 7 are properly included in the rejection.

Claims 1, 4-5, 7 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Graziano et al. (Jour. Immunol., 149, 556, 1992).

Graziano et al. (cited in IDS of 2/11/02) teach a 17-mer polypeptide which corresponds to a T-cell epitope from SIV. They teach substituting A for V at position 100 or V for A at position 110 enhances immunogenicity. Immunogenicity can be further enhanced by addition of A, Q or E residues at the amino terminal, as well as of Y and K residues at the carboxyl terminal. See abstract and page 559 col. 2 for example. They teach such modifications for peptide vaccines. These modifications are consistent with what is recited in instant claims 1, 4-5, 7 and 31.

As with Lipford et al., citation of Graziano et al. is proper, since the term "polypeptide" reasonably encompasses a 17-mer. It is also to be noted that the testing of the relative immunogenicity of the modified peptide in vivo, was only tested in mice of one MHC haplotype (haplotype K of strain CBA/J), as disclosed at page 558, col. 2. It is noted that this is sufficient to anticipate, since the "individual" in claims 1 and 31 can reasonably encompass an individual of a particular haplotype.

Claims 1, 4-5, 7 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Russell-Jones et al. (5,500,366).

Russell-Jones et al. teach peptide sequences representing T-cell epitopes of the TraT protein of E. Coli. Peptides T3, T6 and T7 are modified versions that involve amino acid substitutions; these are more immunogenic than the non-modified peptides. See col. 4, lines 41-50. Claims are rejected following rationale applied to Lipford et al. and Graziano et al. *supra*.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr  
September 30, 2003

*David A. Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT ~~182~~ 1644